

Exhibit 1

David B. Ross, M.D., Ph.D., MBI

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

KATRINA DAWN COPLEY,	:	Civil Action No.
Plaintiff,	:	3:14-cv-00406
v.	:	
BAYER HEALTHCARE	:	
PHARMACEUTICALS, INC., BAYER	:	
PHARMA AG, and BAYER OY,	:	
Defendants.	:	

VIDEOTAPED DEPOSITION OF
DAVID B. ROSS, M.D., Ph.D., M.B.I.
Baltimore, Maryland
Friday, April 8, 2016
9:00 a.m.

Reported by: Linda S. Kinkade RDR CRR RMR CSR

David B. Ross, M.D., Ph.D., MBI

Page 2	Page 4
<p>1 The following is the transcript of the</p> <p>2 videotaped deposition of DAVID B. ROSS, M.D., Ph.D.,</p> <p>3 M.B.I. held at the offices of:</p> <p>4</p> <p>5 Janet Jenner & Suggs</p> <p>6 Commerce Centre East</p> <p>7 1777 Reisterstown Road</p> <p>8 Baltimore, Maryland 21208</p> <p>9</p> <p>10 Taken pursuant to applicable Rules of Civil</p> <p>11 Procedure, before Linda S. Kinkade, Registered</p> <p>12 Diplomate Reporter, Certified Realtime Reporter,</p> <p>13 Registered Professional Reporter, Registered Merit</p> <p>14 Reporter, Certified Shorthand Reporter, as licensed</p> <p>15 by the State of California, and Notary Public, as</p> <p>16 commissioned by the State of Maryland.</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 INDEX OF EXAMINATION</p> <p>2</p> <p>3 EXAMINATION of DAVID B. ROSS, M.D. PAGE</p> <p>4 BY MR. SCHMIDT 10</p> <p>5 407</p> <p>6 BY MS. HORNER 362</p> <p>7 465</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
Page 3	Page 5
<p>1 APPEARANCES:</p> <p>2</p> <p>3 On Behalf of Plaintiff:</p> <p>4 Jones Ward PLC</p> <p>5 By: Lauren Horner, Esquire</p> <p>6 lauren@jonesward.com</p> <p>7 By: Lawrence L. Jones II, Esquire</p> <p>8 larry@jonesward.com</p> <p>9 Marion E. Taylor Building</p> <p>10 312 South Fourth Street, Sixth Floor</p> <p>11 Louisville, KY 40202</p> <p>12</p> <p>13</p> <p>14 On Behalf of Defendants:</p> <p>15 Covington & Burling LLP</p> <p>16 By: Paul W. Schmidt, Esquire</p> <p>17 pschmidt@cov.com</p> <p>18 By: Gregory L. Halperin, Esquire</p> <p>19 ghalperin@cov.com</p> <p>20 One City Center</p> <p>21 850 Tenth Street, NW</p> <p>22 Washington, DC 20001</p> <p>23 Also present:</p> <p>24 David Lane, Video Tech</p>	<p>1 E X H I B I T S</p> <p>2</p> <p>3 NO. DESCRIPTION PAGE</p> <p>4 Exhibit 1 Expert Report of David B. Ross, 11</p> <p>5 M.D., Ph.D., M.B.I.</p> <p>6 Exhibit 2 Plaintiff Katrina Dawn Copley's 17</p> <p>7 Responses to Defendants' Notice</p> <p>8 of Video Deposition of David B.</p> <p>9 Ross, M.D.</p> <p>10 Exhibit 3 David B. Ross Updated 4/7/2016 33</p> <p>11 Journal Articles and Other</p> <p>12 Literature</p> <p>13 Exhibit 4 Expert Witness Retention 34</p> <p>14 Contract</p> <p>15 Exhibit 5 Jacobson/Feigal: Red Sky in the 36</p> <p>16 Morning: Modifying Prescription</p> <p>17 Drug Labels as a Result of</p> <p>18 Postmarket Surveillance</p> <p>19 Exhibit 6 Guidance for Industry: Safety 42</p> <p>20 Labeling Changes Implementation</p> <p>21 of Section 505(o)(4) of the</p> <p>22 FD&C Act</p> <p>23</p> <p>24</p>

2 (Pages 2 to 5)

David B. Ross, M.D., Ph.D., MBI

Page 6			
1	Exhibit 7	Department of Health & Human Services Letter dated 11/12/1992 re changes to the Norplant System label	43
2			
3			
4			
5	Exhibit 8	Invoice dated 2/15/2016 re Mirena from David B. Ross billed to Jones Ward PLC	44
6			
7			
8	Exhibit 9	ISR Age Therapy Event date Calculated ... Ross	59
9			
10		OV 2.0 Results	
11	Exhibit 10	Center for Drug Evaluation and Research Approval Package for Application Number 20-634/S062 and 20-634/S064 Trade Name: Levaquin	71
12			
13			
14			
15			
16	Exhibit 11	MIR_KCOPLEY_JSEU_000000009.xls pages 1-74	76
17			
18	Exhibit 12	Evans: Use of proportional reporting ratios (PRRs) for signal generation from spontaneous adverse drug reaction reports	83
19			
20			
21			
22			
23	Exhibit 13	OpenVigil 2.0 Screenshot	102
24	Exhibit 14	OpenVigil 2.0 Screenshot	103

Page 7			
1	Exhibit 15	OpenVigil a pharmacovigilance data analysis tool	110
2			
3	Exhibit 16	OpenVigil 2.0 Screenshot	122
4	Exhibit 17	OpenVigil 2.0 Screenshot	174
5	Exhibit 18	ARVO 2015 Annual Meeting Abstracts	174
6			
7	Exhibit 19	Berlex Drug Development & Technology August 28, 2000 re: NDA 21-225 Mirena	249
8			
9			
10		MIR_INDNDA_00032125 -	
11		MIR_INDNDA_00032152	
12	Exhibit 20	Suspect Adverse Reaction Report	249
13			
14			
15	Exhibit 21	Berlex Laboratories, Inc. Memorandum dated March 31, 1998 re FDA Minutes of the January 27, 1998 Meeting to Discuss LNG-IUS	278
16			
17			
18			
19			
20		MIR_JR_00010228 -	
21		MIR_JR_00010234	
22	Exhibit 22	Diagram drawn by deponent with curves not to scale for Skyla, Norplant and Mirena	318
23			
24			

Page 8			
1	Exhibit 23	Schering Mirena Excerpt	323
2		Periodic Safety Update Report	
3		MIR_AC_00174527 -	
4		MIR_AC_00174555	
5	Exhibit 24	Therapeutic Advances in Drug Safety Risk of intracranial hypertension with intrauterine levonorgestrel: Reply	348
6			
7			
8			
9	Exhibit 25	Therapeutic Advances in Drug Safety Risk of intracranial hypertension with intrauterine levonorgestrel	349
10			
11			
12			
13	Exhibit 26	OpenVigil Search 4/7/2016 including Text to Columns after Concatenate	367
14			
15			
16	Exhibit 27	Signal Assessment Mirena - Idiopathic intracranial Hypertension (IIH)	384
17			
18		MIR_KCOPLEY_JSEU_0000046 -	
19		MIR_KCOPLEY_JSEU_0000067	
20			
21	Exhibit 28	Master RR Case Number CLINICAL TRIAL CASE	387
22			
23		MIR_KCOPLEY_JSEU_00000022	
24			

Page 9			
1	Exhibit 29	Master RR Case Number Analysis Narrative	392
2			
3		MIR_KCOPLEY_JSEU_00000022	
4			
5			
6			
7			
8			
9			
10			
11			
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3 (Pages 6 to 9)

Golkow Technologies, Inc. - 1.877.370.DEPS

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David B. Ross, M.D., Ph.D., MBI

Page 38	Page 40
<p>1 A. From 2007.</p> <p>2 Q. It's an article by Dr. Feigal on</p> <p>3 pharmacovigilance and the role of the FDA, correct?</p> <p>4 A. I would say, in terms of the issues he</p> <p>5 discusses, I would say he does have expertise in</p> <p>6 this area.</p> <p>7 Q. In the areas of pharmacovigilance and</p> <p>8 the FDA.</p> <p>9 A. Yes.</p> <p>10 Q. And he's someone -- you look to his</p> <p>11 publications in thinking through your opinions?</p> <p>12 MS. HORNER: Object to form.</p> <p>13 THE WITNESS: I would say there are --</p> <p>14 there's information in here that I find useful.</p> <p>15 BY MR. SCHMIDT:</p> <p>16 Q. Did you know it before you read it in</p> <p>17 Dr. Feigal's article, the information that you</p> <p>18 found useful?</p> <p>19 MS. HORNER: Object to form.</p> <p>20 THE WITNESS: I certainly knew it on the</p> <p>21 basis of my own experience, but it's always helpful</p> <p>22 to have somebody who expresses the same view.</p> <p>23 BY MR. SCHMIDT:</p> <p>24 Q. Okay. Did you know Dr. Feigal at the</p>	<p>1 A. Yes.</p> <p>2 Q. Was he -- did you -- were you in a</p> <p>3 reporting chain with him?</p> <p>4 A. Yes.</p> <p>5 Q. How direct was the reporting chain?</p> <p>6 A. It was a couple levels removed.</p> <p>7 Q. So he was a couple levels above you at</p> <p>8 the FDA, Dr. Feigal was?</p> <p>9 A. Yes.</p> <p>10 Q. Did you ever, given your experience with</p> <p>11 him, have reason -- well, strike that.</p> <p>12 You understand that the FDA is a consumer</p> <p>13 protection agency.</p> <p>14 A. Among other functions, yes.</p> <p>15 Q. Yes. And that its job is on behalf of</p> <p>16 the United States federal government to regulate</p> <p>17 the safety and efficacy of -- of drugs.</p> <p>18 A. That is its statutory mission.</p> <p>19 Q. Did you ever have concern about, based</p> <p>20 on your experience with Dr. Feigal, about his</p> <p>21 dedication to performing those missions?</p> <p>22 MS. HORNER: Objection to form. I</p> <p>23 believe he said he doesn't remember much.</p> <p>24 MR. SCHMIDT: Please don't coach.</p>
Page 39	Page 41
<p>1 FDA?</p> <p>2 A. Yes.</p> <p>3 Q. And did you know him personally?</p> <p>4 A. Yes.</p> <p>5 Q. Did you know him to be dedicated at the</p> <p>6 FDA to patient safety from your experience with</p> <p>7 him?</p> <p>8 A. I'm -- it was almost 20 years ago, so</p> <p>9 bear with me. The only -- to be honest with you,</p> <p>10 the only -- and, again, this is 20 years ago. I</p> <p>11 had started there in '96. He was the office</p> <p>12 director at the microbial office.</p> <p>13 The only conversation I remember being part</p> <p>14 of with him is one in which he pointed out that the</p> <p>15 manufacturer of thalidomide, which is a drug, as we</p> <p>16 all know, that's associated with severe birth</p> <p>17 defects, had never admitted that the drug caused</p> <p>18 birth defects despite overwhelming evidence. I</p> <p>19 will say that in 2012 the successor company, which</p> <p>20 I believe was Grunenthal, did finally admit that</p> <p>21 thalidomide was associated with that adverse event.</p> <p>22 Q. Let me -- I don't want to take us on a</p> <p>23 detour. Was he senior to you at the FDA when you</p> <p>24 were there together, Dr. Feigal?</p>	<p>1 THE WITNESS: I -- I can't -- I can't</p> <p>2 recall any specific issues. Again, this was a long</p> <p>3 time ago.</p> <p>4 BY MR. SCHMIDT:</p> <p>5 Q. Have you come across him since other</p> <p>6 than in this case?</p> <p>7 A. There's a previous case in which we were</p> <p>8 retained by counsel for different sides on a case.</p> <p>9 Q. I've marked as Exhibit -- what was that</p> <p>10 case?</p> <p>11 A. That was Wendell versus</p> <p>12 Johnson & Johnson, Teva Pharmaceuticals and Abbott,</p> <p>13 I believe.</p> <p>14 Q. What was the product or the drug</p> <p>15 involved in that case?</p> <p>16 A. Well, there were multiple products.</p> <p>17 There was Remicade, Humira and 6-mercaptopurine.</p> <p>18 Q. Were you testifying on behalf of the</p> <p>19 plaintiffs or defendants?</p> <p>20 A. Plaintiffs.</p> <p>21 Q. How many times have you testified on</p> <p>22 behalf of plaintiffs, either by preparing a report</p> <p>23 or giving a deposition or testifying at trial?</p> <p>24 MS. HORNER: Objection to form.</p>

11 (Pages 38 to 41)

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David B. Ross, M.D., Ph.D., MBI

<p style="text-align: right;">Page 466</p> <p>1 - - - - -</p> <p>2 E R R A T A</p> <p>3 - - - - -</p> <p>4</p> <p>5 PAGE LINE CHANGE</p> <p>6 _____</p> <p>7 REASON: _____</p> <p>8 _____</p> <p>9 REASON: _____</p> <p>10 _____</p> <p>11 REASON: _____</p> <p>12 _____</p> <p>13 REASON: _____</p> <p>14 _____</p> <p>15 REASON: _____</p> <p>16 _____</p> <p>17 REASON: _____</p> <p>18 _____</p> <p>19 REASON: _____</p> <p>20 _____</p> <p>21 REASON: _____</p> <p>22 _____</p> <p>23 REASON: _____</p> <p>24 _____</p>	<p style="text-align: right;">Page 468</p> <p>1 C E R T I F I C A T E</p> <p>2</p> <p>3 I, LINDA S. KINKADE, Registered Diplomate</p> <p>4 Reporter, Certified Realtime Reporter, Registered</p> <p>5 Merit Reporter, Certified Shorthand Reporter, and</p> <p>6 Notary Public, do hereby certify that prior to the</p> <p>7 commencement of examination the deponent herein was</p> <p>8 duly sworn by me to testify truthfully under</p> <p>9 penalty of perjury.</p> <p>10 I FURTHER CERTIFY that the foregoing is a</p> <p>11 true and accurate transcript of the proceedings as</p> <p>12 reported by me stenographically to the best of my</p> <p>13 ability.</p> <p>14 I FURTHER CERTIFY that I am neither counsel</p> <p>15 for nor related to nor employed by any of the</p> <p>16 parties to this case and have no interest,</p> <p>17 financial or otherwise, in its outcome.</p> <p>18 IN WITNESS WHEREOF, I have hereunto set my</p> <p>19 hand and affixed my notarial seal this 11th day of</p> <p>20 April 2016.</p> <p>21 My commission expires: July 31, 2017</p> <p>22 _____</p> <p>23 NOTARY PUBLIC IN AND FOR</p> <p>24 THE DISTRICT OF COLUMBIA</p>
<p style="text-align: right;">Page 467</p> <p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2</p> <p>3 I, _____, do</p> <p>4 hereby certify that I have read the</p> <p>5 foregoing pages, and that the same is</p> <p>6 a correct transcription of the answers</p> <p>7 given by me to the questions therein</p> <p>8 propounded, except for the corrections or</p> <p>9 changes in form or substance, if any,</p> <p>10 noted in the attached Errata Sheet.</p> <p>11</p> <p>12</p> <p>13 _____</p> <p>14 DAVID B. ROSS, M.D., PH.D., MBI DATE</p> <p>15</p> <p>16</p> <p>17 Subscribed and sworn</p> <p>18 to before me this</p> <p>19 _____ day of _____, 20____.</p> <p>20 My commission expires: _____</p> <p>21</p> <p>22 _____</p> <p>23 Notary Public</p> <p>24</p>	

118 (Pages 466 to 468)